DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 31, 2016

AngioScore, Inc.
c/o Gary Gershony, M.D.
Chief Medical Officer
965 Atlantic Ave. Suite 101
Alameda, CA 94501

Re: K050629
Trade/Device Name: AngioSculpt™ Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: PNO
Dated: August 10, 2005
Received: August 10, 2005

Dear Dr. Gershony:

This letter corrects our substantially equivalent letter of September 2, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K050629

Device Name: **AngioSculpt® Scoring Balloon Catheter**

Indications for Use:

The AngioSculpt Scoring Balloon Catheter is intended for balloon dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050629

510(k) Summary

SEP 0 2 2005

[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

Manufacturer
AngioScore, Inc.
965 Atlantic Avenue, Suite 101
Alameda, CA 94501

Contact Person
Gary Gershony, MD, FACC
Chief Medical Officer
Tel: 510-263-0480; Fax: 510-263-0481

2. General Information

Trade Name	AngioSculpt® Scoring Balloon Catheter
Common / Usual Name	Angioplasty catheter
Classification Name	Catheter, angioplasty, peripheral, transluminal (LIT)
Predicate Devices	Cordis Aviator® PTA Dilatation Catheter (K013581) Cordis Savvy® PTA Dilatation Catheter (K971010)

3. Intended Use / Indications

The AngioSculpt Scoring Balloon Catheter is intended for balloon dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

4. Device Description

The AngioSculpt Scoring Balloon Catheter is a standard two-lumen catheter with a scoring balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

5. Substantial Equivalence Comparison

There is no difference between the AngioSculpt catheter intended use and that of predicate devices. The AngioSculpt catheter materials and sizes are similar to currently marketed balloon angioplasty catheters and guide wires. The AngioSculpt catheter configuration is similar to the predicate and other peripheral balloon angioplasty catheters. The main difference is the presence of the spiral scoring element on the AngioSculpt catheter. The scoring element functions similar to a "buddy-wire" to focus forces generated by balloon expansion to assist with dilation of resistant lesions. Performance testing demonstrated that the AngioSculpt catheter reliably achieves the desired affect and is safe for its intended use. No new questions of safety or effectiveness for peripheral balloon angioplasty devices were raised during the testing. The AngioSculpt Scoring Balloon Catheter is, therefore, substantially equivalent to currently marketed devices.